

### Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 02/10/09 has been entered.

### Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 02/10/09 in response to the final Office Action mailed 08/20/08.

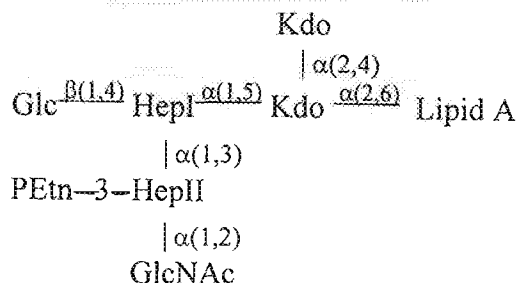
### Examiner's Amendment

3) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. David Hayzer in a telephonic interview on 28 April 2009.

This application has been amended as indicated below:

- (a) Claims 62-100 have been canceled.
- (b) New claims 101-106 have been added as indicated below.

--Claim 101 (New). A method of eliciting in a subject an antibody that binds to the lipopolysaccharide (LPS) inner core of L3, L1, L7, L8, L9, L10, L11 and L12 immunotypes of *Neisseria meningitidis* comprising administering to said subject an immunogenic composition comprising the LPS inner core of *galE* mutant of *Neisseria meningitidis* immunotype L3, wherein the LPS inner core of the *galE* mutant has the formula:



and comprises an LPS inner core epitope wherein a phosphoethanolamine moiety is linked to the 3-position of HepII of the LPS inner core, wherein said epitope is specifically recognized by the monoclonal antibody B5 produced by the hybridoma deposited with the accession number IDAC 260900-1.

Claim 102 (New). The method of claim 101, wherein the LPS inner core of the *galE* mutant does not comprise LPS outer core.

Claim 103 (New). The method of claim 101, wherein the LPS inner core epitope is accessible in the presence of capsule or LPS outer core of said *Neisseria meningitidis*.

Claim 104 (New). The method of claim 101, wherein the antibody elicited does not bind to the LPS inner core of *Neisseria meningitidis* immunotypes L2, L4, L5 and L6.

Claim 105 (New). The method of claim 101, wherein the immunogenic composition is a conjugate.

Claim 106 (New). The method of claim 101, wherein the monoclonal antibody B5 has opsonic activity against a wild type *Neisseria meningitidis* strain comprising an LPS inner core epitope wherein a phosphoethanolamine moiety is linked to the 3-position of HepII of the LPS inner core, and a *galE* mutant thereof.

### **Status of Claims**

- 4) Claims 48-61 have been canceled via the amendment filed 02/10/09.  
New claims 62-100 have been added via the amendment filed 02/10/05.  
New claims 101-106 have been added via this examiner's amendment.  
Claims 101-106 are pending and are under examination.

### **Oath/Declaration**

- 5) The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required. See the uninitialed hand-written changes made to the address of inventor Joyce Plested and Michael P. Jennings.

### **Rejection(s) Moot**

- 6)** The rejection of claims 48, 55, 62-70, 72-76 and 78-81 made in paragraph 9 of the Office Action mailed 07/30/07 and maintained in paragraph 10 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of the cancellation of the claims.
- 7)** The rejection of claims 48, 55, 70 and 76 made in paragraph 11 of the Office Action mailed 07/30/07 and maintained in paragraph 11 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 8)** The rejection of claims 62, 66 and 78 made in paragraph 10(d) of the Office Action mailed 07/30/07 and maintained in paragraph 12 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 9)** The rejection of claims 63, 67, 73 and 79 made in paragraph 10(e) of the Office Action mailed 07/30/07 and maintained in paragraph 13 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 10)** The rejection of claims 75 and 81 made in paragraph 10(f) of the Office Action mailed 07/30/07 and maintained in paragraph 14 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 11)** The rejection of claims 48, 55, 70 and 76 made in paragraph 10(g) of the Office Action mailed 07/30/07 and maintained in paragraph 15 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 12)** The rejection of claims 62-69, 72-75 and 78-81 made in paragraph 10(h) of the Office Action mailed 07/30/07 and maintained in paragraph 16 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 13)** The rejection of claims 48, 55, 62-70, 72-76 and 78-81 made in paragraph 11 of the Office Action mailed 07/30/07 under 35 U.S.C. § 102(b) as being anticipated by van der Ley *et al.* (*Mol. Microbiol.* 19: 1117-1125, 1996, already of record) as evidenced by Poolman JT (*Infectious Agent and Disease* 4: 13-28, 1995, already of record) and Vogel *et al.* (*Microbiol. Immunol.* 186: 159-

166, October 1997, already of record) or van der Ley *et al.* (*Vaccine* 13: 401-407, 1995, already of record) (van der Ley *et al.*, 1995) and maintained in paragraph 17 of the Office Action mailed 08/20/08 is moot in light of the cancellation of the claims.

### Remarks

**14)** Claims 101-106, now renumbered as claims 1-6 respectively, are allowed.

Claims 101-106 find descriptive support in the paragraph bridging pages 33 and 34; original claims; second full paragraph on page 34; the top panel of Figure 3; Figures 2 and 1; Example 1; and pages 52 and 56 of the instant specification.

**15)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**16)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**17)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/  
Primary Examiner  
AU 1645  
April, 2009